

## REMARKS

The Office Action mailed March 27, 2007 has been received and reviewed. All pending claims stand rejected. The application is to be amended as previously set forth. All amendments are made without prejudice or disclaimer. Basis for the amendments to claims 1 and 10 may be found throughout the application, but specific basis can be found in paragraph [0007] of the as-filed specification. No new matter has been added. Reconsideration is respectfully requested.

### A. Personal Interview:

Applicant is submitting this document to maintain the pendency of the application and for use at the personal interview scheduled for October 3, 2007 at 3:00 p.m. At the interview, the desirability of a potential Declaration confirming unexpected results arising from the disclosure will also be discussed.

### B. 35 U.S.C. § 103:

Claims 1 through 3 and 5 through 20 stand rejected as assertedly being obvious over Wilson et al. in view of Mahan. Applicants respectfully traverse the rejection.

Claim 1 defines “an animal feed suitable for feeding a gestating animal and which improves the fertility of an animal fed said animal feed, which feed comprises an amount of lysine and the following amino acids in an amount relative to the amount of lysine (w/w) in the following ranges: total methionine + cysteine: >0.55; threonine: >0.60; tryptophan: >0.15; and arginine: >1.5, wherein a daily dosage of at least 200 mg arginine per kg body of the gestating animal (kgbw) is provided upon feeding.”

To establish a *prima facie* case of obviousness the prior art references, when combined, must teach or suggest all of these claim elements. *In re Royka*, 490 F.2d 981, 985 (CCPA 1974); *see also* MPEP § 2143.03. Additionally, there must be “a reason that would have prompted a person of ordinary skill in the relevant field to combine the [prior art] elements” in the manner claimed. *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1742, 167 L.Ed.2d 705, 75 USLW 4289, 82 U.S.P.Q.2d 1385 (2007). Further, to establish a *prima facie* case of obviousness, there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 1097 (Fed. Cir. 1986). Underlying the obvious determination is the fact that statutorily prohibited hindsight

cannot be used. *KSR*, 127 S.Ct. at 1742.

Wilson teaches animal feed compositions and methods for increasing the reproductive performance of breeding populations of swine. Wilson's invention is directed to a method of increasing reproductive performance of female swine by administering  $\omega$ -3-fatty acids to the swine. (*See, e.g.*, claim 1 of Wilson). Wilson teaches incorporating their invention into "any animal feed blend known in the art" including "rapeseed meal, cottonseed meal; soybean meal, and cornmeal". Such animal feed blends can include, as "optional amino acid ingredients", "arginine, histidine, isoleucine, leucine, lysine, methionine, threonine, tryptophan, valine, tyrosine ethyl HCl, alanine, aspartic acid, sodium glutamate, glycine, proline, serine, and cysteine ethyl HCl, and analogs." (Paragraph 0031). No further mention of arginine is made in Wilson. Wilson also teaches several methods of administration ranging from feeding the composition to the animals daily for their lifetime, to feeding the composition to an animal before and/or during pregnancy and/or during lactation, and so on (paragraph 0030).

However, as admitted by the Office, Wilson does not teach the specific amounts of amino acids recited by applicants' claims. (Office Action, p. 3).

Wilson's lack of disclosure in this regard is particularly striking with respect to the amount of arginine. Specifically, Wilson does not teach or suggest modifying the amount of arginine (or lysine to arginine ratio) at all in their feed or any effect such a modification might have with respect to improving fertility. Wilson further does not disclose applicants' particularly claimed amounts of arginine (*e.g.*, "an animal feed suitable for feeding a gestating animal, which feed comprises an amount of lysine and [arginine] in an amount relative to the amount of lysine (w/w) [of] arginine >1.5, wherein a daily dosage of at least 200 mg arginine per kg body of the gestating animal (kgbw) is provided upon feeding."

In view of this missing element, the Office relies on Mahan. "Mahan teaches that soybean meal contains amino acids including arginine, lysine, methionine, threonine, tryptophan, and cysteine and provides percentage amounts for each amino acid (Table 2). Mahan also teaches that soybean meal naturally contains 0.20% calcium (Table 2)." The Office then asserts (and applicants dispute) that "one of ordinary skill in the art would have been motivated to optimize the particular amounts of amino acids in the composition taught by Wilson by way of routine experimentation" (presumably to applicants' claimed amounts). The Office continues

that “absent unexpected results, a practitioner would reasonably expect an animal feed composition to provide the same result as suggested by Wilson; to increase the reproductive performance of breeding populations of swine. Thus in Wilson, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the animal feed composition.”

First, this argument overlooks Wilson’s primary teaching, *i.e.*, that omega-3 fatty acids enhance fertility. There is nothing in Wilson which would suggest that modifying the arginine or other “optional” amino acid concentration of the feed would improve the fertility of an animal fed the animal feed, which is an aspect of the amended claims.

Second, in regard to Mahan, Table 2 of Mahan illustrates the composition of soybean meal as including 3.56% arginine, 2.97 % lysine, 0.65% methionine, 0.76% cysteine, 1.83% threonine and 1.70% tryptophan. Relative to the amount of lysine, this gives a total amount of methionine and cysteine of less than 0.55 ( $0.65 + 0.76/2.97 = 0.47$ ). The weight ratio between arginine and lysine is lower than 1.5 ( $(3.56/2.97 = 1.20)$ ). The Examiner acknowledges that Mahan also does not teach or suggest the claimed relative amounts of amino acids or the benefit on fertility. Thus, the combination of Wilson et al. and Mahan fails to teach or suggest every element of the presently claimed invention, and a *prima facie* case of obviousness has not been made.

To overcome this shortcoming, it is evidently the position of the Office that since soybean meal naturally contains amino acids, it would be obvious to one of skill in the art to increase the relative amount of such amino acids to achieve the ratios of the presently claimed invention. However, Wilson *et al.* and Mahan do not provide any suggestion or motivation to modify or combine the references or modify them to the ratios of the claims. Wilson is silent regarding any benefit of an increased ratio of methionine/cysteine to lysine and arginine to lysine. One skilled in the art would thus not be motivated to experiment with the *relative ratios* of these amino acids in the soybean meal of Mahan. Without any motivation, one skilled in the art would not know what changes to make, or what the benefits would be of making such changes, in the formulation of the soybean meal animal feed blend in order to achieve the claimed invention.

The combination of Wilson and Mahan fails to teach or suggest a composition having the claimed ratio of methionine/cysteine to lysine and arginine to lysine or a method which includes

providing a diet to at least one gestating animal resulting in a daily dosage of 200 - 1300 mg arginine per kg body weight of at least one gestating animal. Further, the references are silent as to any potential benefit of increasing arginine or the methionine/cysteine to lysine and arginine to lysine ratios. As increasing the amount or ratio of these amino acids would significantly increase the cost of the composition, one of skill in the art would not be motivated to make such a composition without being aware of the potential benefit of the investment.

Although these points were acknowledged in the Office action, the Office stated that any recitation of intended use does not alone shown patentable distinction. (Office Action, p. 4). The standard being asserted is not, however, the proper one. It may be the standard for a composition that is already known (*i.e.*, anticipated), but is not the standard for one that is merely asserted to be obvious as is admittedly the case here. (*See, e.g., In re Sullivan*, ---F.3d---, 2007 WL243384 1 (Fed. Cir. 2007)) (Reversing the Board of Patent Appeals and Interferences and acknowledging that “[w]hile a statement of intended use may not render a known composition patentable, the claimed composition was not known, and whether it would have been obvious depends upon consideration of the rebuttal evidence.”)

Further,

It is well settled that the PTO “bears the initial burden of presenting a prima facie case of unpatentability. . . . However, when a prima facie case is made [which applicants do not admit in the present case], the burden shifts to the applicant to come forward with evidence and/or argument supporting patentability.” *In re Glaug*, 283 F.3d 1335, 1338 (Fed. Cir. 2002). Rebuttal evidence is “merely a showing of facts supporting the opposite conclusion.” *In re Piasecki*, 745 F.2d 1468, 1472 (Fed. Cir. 1984). Evidence rebutting a prima facie case of obviousness can include: “evidence of unexpected results,” *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1369 (Fed. Cir. 2007), evidence “that the prior art teaches away from the claimed invention in any material respect,” *In re Peterson*, 315 F.3d 1325, 1331 (Fed. Cir. 2003). . . . When a patent applicant puts forth rebuttal evidence, the Board must consider that evidence. *See In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995) (stating that “all evidence of nonobviousness must be considered when assessing patentability”); *In re Sernaker*, 702 F.2d 989, 996 (Fed. Cir. 1983) (“If, however, a patent applicant presents evidence relating to these secondary considerations, the [Office] must always consider such evidence in connection with the determination of obviousness.”).

*Id.*

As part of a rebuttal case, applicants point out that a person of skill in the art would not

have been motivated to increase the amount (or relative ratio) of arginine in a feed composition as the National Research Council (NRC), a standard handbook reference for swine breeders, states that swine during pregnancy synthesize all the necessary arginine. (Specification, page 3, lines 9-21). According to this reference, excessive supplements of arginine are undesirable as they can reduce feed intake and reduce growth. As such, one of ordinary skill in the art would not have had a reasonable expectation of success by increasing the arginine content of the feed. This reference constitutes a "teaching away" from applicants' invention. It certainly substantiates applicants' assertion of "unexpected results".

In conclusion, a *prima facie* case of obviousness has not been established because the cited references do not alone, or in combination, teach or suggest each and every element of any of claims 1-3 and 5-20. Moreover, applicants respectfully submit that one of ordinary skill in the art would not have been motivated to combine the cited references and, in light of the NRC report, one of ordinary skill in the art would have been taught away from combining the cited references. Therefore, it is requested that the rejection of claims 1-3 and 5-20 under 35 U.S.C. § 103(a) be withdrawn.

If questions remain after consideration of the foregoing, the Office is kindly requested to contact applicants' attorney at the address or telephone number given herein.

Respectfully submitted,



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Date: September 27, 2007